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ROGER M. RATHBUN
13 MARGARITA COURT
HILTON HEAD ISLAND, SC 29926

EXAMINER

MCCROSKY, DAVID J

ART UNIT PAPER NUMBER

3736

DATE MAILED: 12/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/078,903

Applicant(s)

BAKRY, MOHAMED

Examiner

David J. McCrosky

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13-21, 27-30 and 32 is/are rejected.
- 7) ☒ Claim(s) 10-12, 22-26, 31 and 33 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 17-31 have been renumbered 19-33.

Claims 1, 13, 19 and 27 are objected to because of the following informalities: it appears that "plural" in line 1 of claims 1 and 13 should read --pleural--; regarding claims 1 and 13, 37 CFR 1.75(i) requires that each element of the claim should be separated by a line indentation; there are two periods at the end of claim 19; and it appears that "locate" in line 7 of claim 27 should read --located--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "said upper legs" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Ritchart et al. Ritchart et al teach a biopsy needle comprising an outer tube (98b) and an inner tube (100b) axially movable within the outer tube (98b). An articulating member (142, 144) is movable between a retracted position and an extended position through an opening in the outer tube (98b). Manipulation of the proximal end of the inner tube actuates the articulating member (142, 144). The distal end of the outer tube (98b) is pointed. A handle (14) is located at the proximal end of the inner tube (100b). See col. 15, ll. 6-45 and Figs. 29-34.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon. Yoon teach a biopsy needle comprising an outer tube (286) and an inner tube (284) axially movable within the outer tube (286). An articulating member (287) is movable between a retracted position and an extended position through an opening in the outer tube (286). Manipulation of the proximal end of the inner tube actuates the articulating member (287). A handle (289) is located at the proximal end of the inner tube (284). See col. 14, l. 60 to col. 15, l. 51 and Figs. 26 and 27.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Follmer et al. The reference discloses a biopsy needle comprising an outer tube (12) and an inner tube (37) axially movable within the outer tube (12). An articulating member (20) is movable between a retracted position and an extended position through an opening in the outer tube (12). Manipulation of the proximal end of the inner tube (37) actuates the articulating member (20). The distal end (24) of the outer tube (12) is pointed. A handle (36) is located at the proximal end of the inner tube (37). See col. 5 and Figs. 1-4. While the inner tube (37) is described as a rod, it would have been an obvious matter of design choice to modify the rod with a tube since Applicant has not disclosed that using a tube solves any stated problem or is for any particular purpose and it appears that the apparatus would perform equally well with an axially movable actuating mechanism of any type.

Regarding claims 7-9, while only one articulating member is disclosed, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a second articulating member, since it has been held that that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krag. The reference discloses a biopsy needle comprising an outer tube (320) and an inner tube (304) axially movable within the outer tube (320). An articulating member (310) is movable between a retracted position and an extended position through an opening (330) in the outer tube (320). The distal end (326) of the outer tube (320) is pointed. A handle (305) is located at the proximal end of the inner tube (304). See col. 17, l. 60 to col. 18, l. 21 and Figs. 12 and 13. While the inner tube (304) is described as a rod, it would have been an obvious matter of design choice to modify the rod with a tube since Applicant has not disclosed that using a tube solves any stated problem or is for any particular purpose and it appears that the apparatus would perform equally well with an axially movable actuating mechanism of any type.

Claims 13 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon in view of Marini. Yoon teach a biopsy needle comprising an outer tube (286) and an inner tube (284) axially movable within the outer tube (286). An articulating member (287) is movable between a retracted position and an extended position through an opening in the outer tube (286). Manipulation of the proximal end of the inner tube actuates the articulating member (287). A handle (289) is located at the proximal end of the inner tube (284). See col. 14, l. 60 to col. 15, l. 51 and Figs. 26 and 27. An outer tube cover is illustrated in Fig. 26. Yoon does not teach an end tube. However, Marini discloses a removeable end tube (22) to allow usage of various end effectors. See Figs. 2-6. It would have been obvious to one of ordinary skill in the art at

the time the invention was made to modify the biopsy needle of Yoon with the end tube of Marini to allow usage of various end effectors.

Regarding claim 18, the above combination does not teach wings. It would have been an obvious matter of design choice to modify the outer tube cover with wings since Applicant has not disclosed that using wings solves any stated problem or is for any particular purpose and it appears that the apparatus would perform equally well with a means for gripping of any type.

Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (cited by Applicant) in view of Ritchart et al. Wang discloses a method of obtaining a biopsy sample from the pleural cavity of a patient. Wang does not disclose a needle having an articulating member. Ritchart et al teach a biopsy needle that operates with maximum efficiency in all tissue environments. See col. 2, ll. 50-55. The biopsy needle comprises an outer tube (98b) and an inner tube (100b) axially movable within the outer tube (98b). An articulating member (142, 144) is movable between a retracted position and an extended position through an opening in the outer tube (98b). Manipulation of the proximal end of the inner tube actuates the articulating member (142, 144). See col. 5 and Figs. 1-4. The distal end of the outer tube (98b) is pointed. A handle (14) is located at the proximal end of the inner tube (100b). See col. 15, ll. 6-45 and Figs. 29-34. The needle is rotated by a thumbwheel. See col. 2, l. 66 to col. 3, l. 2. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Wang with the biopsy needle of Ritchart et al to

provide an alternate biopsy needle that operates with maximum efficiency in all tissue environments.

Claims 27 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (cited by Applicant) in view of Follmer et al. Wang discloses a method of obtaining a biopsy sample from the pleural cavity of a patient. Wang does not disclose a needle having an articulating member. Follmer et al disclose a biopsy needle comprising an outer tube (12) and an inner tube (37) axially movable within the outer tube (12). An articulating member (20) having a cutting edge is movable between a retracted position and an extended position through an opening in the outer tube (12). The distal end (24) of the outer tube (12) is pointed. See col. 2, ll. 13-35 and col. 5 and Figs. 1-4. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Wang with the biopsy needle of Follmer et al to provide an alternate means for sampling tissue in a variety of body lumens.

Allowable Subject Matter

Claims 10-12, 22-26, 31 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 14 and 15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach articulating members having a brush edge nor does

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the prior art teach an elongated opening to stabilize the axial movement of the inner tube; the combination of an end tube with two articulating members having a cutting edge is not taught.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. McCrosky whose telephone number is 703-305-1331. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DJM


MAX F. HINDENBURG
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